IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Examiner Lyle A. Alexander ART UNIT 1743

In re application of E. Alan Bates et al. Application No. 08/935,629 Filed 09/23/97 For ASSAYING DEVICE ....

#### DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents Washington, DC 20231

- I, Gary Hoffman, declare as follows:
- I am the third joint inventor for this application.
- 2. While the claims of this application have been rejected based on the patent of Senior, the disclosure of the applications starts from a technology actually quite different from that of Senior. Characteristic of this difference is Senior's provision of its bibulous member 16 protruding out of the housing. When the bibulous member is placed in a urine stream, it is quickly soaked. Senior has correctly chosen to display this version in its drawings, because versions such as suggested in paragraph a. in col. 5 of Senior would tend to shield the bibulous member from a urine stream.
- 3. This application references in its BACKGROUND a quite different technology, that of drug testing using an immunoassay method called antigen-antibody competitive binding. Characteristic of this technology is the measured application of only a few drops of urine. This dropwise application of the urine is disclosed in the specification in the first paragraph of the DETAILED DESCRIPTION OF THE INVENTION.
  - 4. Attached hereto are Exhibits 1 to 5 demonstrating five different instances of the type

rom Sullivan To: Ext. Lyle Alexander Date: \$725/04 Time: 2:45:00 PM Page 9 of 33

of technology forming the starting point for this application. These are as follows:

Exhibit 1 - Pages 1-4 of a document entitled "AccuSign DOA 4, THC/OPI/COC/AMP" bearing copyright notice dated 1996;

Exhibit 2 - Pages 1-4 of a document entitled "AccuSign BAR", also bearing copyright notice dated 1996:

Exhibit 3 - Front and back of a leaflet headed "Drug Test Resources International", likewise concerning AccuSign DOA 4 and bearing a 1996 copyright notice:

Exhibit 4 - One-sided, undated leaflet headed "Visaline II"; and

Exhibit 5 - Copies of the packages of several kits labeled HOME DRUG TEST and their instruction leaflets.

- Exhibit 1 is noteworthy for the correspondence of the terminology in its section
   Principle on its page 1 with the terminology in the BACKGROUND section of this application.
- 6. All of the exhibits direct that 3 drops of urine be applied, this being a standard for this rechology. All of the exhibits provide either a dropper or a pipette for transfer of the urine sample into the sample well. In each of the exhibits, the sample receiving area is clearly a well, and Exhibit 1, for instance, calls it a "well" in the section Test Protocol on its page 2.
- 7. The chart at the top of page 2 of Exhibit 1, for instance, explains that appearance of a line for a particular drug in this starting technology is a negative indication, i.e. the drug is not present in amounts above the cutoff level.
- 8. A characteristic of this technology is that the sample collection location must not be flooded with urine, as in Senior, because this leads to false positives by washing out the lines that would otherwise indicate negative readings.

FAX NO. : 412-821-2428

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- 9. It is to be noted that none of these exhibits mentions photocopying the results. The statements regarding photocopying in the BACKGROUND section of the present application represent perceptions of the present inventor group, rather than the state of the art at the time mis invention was made.
- 10. While the provision of a cap to cover Senior's wet, protruding member 16 is impediately understandable, it was the present group of inventors which perceived the advantages of such for the different technology from which the present invention arose.
- 11. A difference between the present invention and Senior concerns the problem with putting a cap on Senior's test. Because the bibulous material can be so flexible (especially when wet) there often is difficulty slipping the cap on without bending the material. It's like threading a needle by holding the thread still and moving the needle
- 12. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; such statements were made with the knowledge that willful false statements and the like so made are punushable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issued thereon.

Jany Dete: 8-21-00

# AccuSign™ DOA 4 THC/OPI/COC/AMP

One-Step Panel Assay for Drugs of Abuse

For In Vitro Use Only

Simple One-Step Immunoassay for the Qualitative Detection of THC metabolites. Opiates, Cocaine metabolite, Amphetamines, and/or their Metabolites in Urine

### PBM DOA-240

Catalog No.

35 Test Kir. DOA-240-10 10 Test Kit

50 ng/mL

300 ng/mL

#### Intended Use

The AccuSign" DOA 4 THC/OPI/COC/AMP Panel Assay is a simple, one-step immunochromatographic test for the rapid, qualitative detection of THC metabolites, opiates, cocaine metabolite, and amphetamines in urine. The test detects the major metabolites of these drugs at the following cutoff concentrations

THC 11-nor-Δ\*-THC-9-carboxylic acid OPI Morphine

COC Benzoylecgonine AMP Amphetamine

300 ng/mL 1000 ne/mI The Accusion DOA & THE OPPICOC/AMP test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to oblain a confirmed analytical

result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmatory methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result. particularly when preliminary positive results are used.

#### Summary and Explanation

Drug abuse has become one of the most destructive social problems in recent years, affecting nearly every comer of the world. To effectively combat this increasingly disturbing problem, there is a strong need for a simple, rapid, inexpensive, disposable, visual, and non-instrument requiring drug screening test kit. According to the National Institute on Drug Abuse (NIDA), THC (Manijuana), Opiates, Cocame, and Amphetamines are among the most widely abused drugs. The one-step AccuSign" DOA 4 Panel Assay is a test for screening these four major drugs of abuse in urine, simultaneously with one sample application. The sest takes less than 10 minutes to perform

THC (A'-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When ingested or smoked, it produces suphoric effects. Users experience impairment of short term memory and THC use slows learning. Also, it may cause transient episodes of confusion, anxiety, or frank toxic delirium. Long term, relatively heavy use may be associated with behavioral disorders. The peak

effect of smoking THC occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urmary metabo lites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ\*-terrahydrocannabinol-9-carboxylic acid

Opioid analgesies comprise a large group of substances which control pain by depressing the central nervous system. Morphine is the prototype compound of this group. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose

Cocaine, derived from the leaves of coca plant, is a potent central nervous system (CNS) stimulant and a local anesthetic. Cocaine induces euphona, confidence and a sense of increased energy in the user, these psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is used by smoking, intravenous, intranasal or oral administration, and excreted in the urine primarily as benzoyleogonine in a short time Benzoylecgonine has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours) and can generally be detected for 24-60 hours after cocaine use or exposure.44

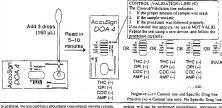
Amphetamine is a potent sympathomametic agent with therapeutic applications. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, paranoia, hallacinations, psychotic behavior, and eventually, depression and exhaustion. The effects of amphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body. Amphetamine is excreted in the unne in unchanged form and also as hydroxylated and deaminated derivatives.

#### Principle

The AccuSign DOA I test employs one-step, solid-phase immunonseay technology to discretely detect the presence of any of the above four drugs, or their immunoreactive metabolites, in urine. The assay uses highly specific monocional/polyclonal antibodies raised against the target drugs. The test card contains a membrane strip, on which each of the four drugs conjugated to BSA is immobilized at specific locations. The assay is based on the principle of the highly specific immunochemical reactions between antigens and antibodies which are used for the unalysis of specific substances in biological fluids. The drug detection relies on the competition for binding to the antibodies between drug conjugates and drugs which may be present in the urine sample.

In the test procedure, a sample of urine is placed in the sample well of the device, and the sample is allowed to migrate upward. If any of the four drugs is present in the urine sample, it forms a complex with the antibody-dye conjugate specific for that drug, and the complex migrates toward the opposite end of the card, passing the specific locations on the membrane where each of the four drug conjugates to immobilized. The drug in the sample competes with the drug conjugate, which is immobilized on the membrane, for the limited antibodies present in the form of antibody-dye eonjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the antibody-dye conjugate cannot bind to the drug conjugate on the membrane. Therefore, a drug-positive urine sample will not generate a line at the specific drug position in the result window, indicating a positive result from positive drug competition. Conversely, if a particular drug is absent in the urine specimen, the antibody on the antibody-dye conjugate will bind the membrane-bound drug. In this case, a drug-negative urine sample will generate a line at the specific drug position in the result window, indicating a negative result from an absence of competition with free drug-

EXHIBIT



in the upper control line area. The control line is immobilized with polyclonal anti-mouse antibody: therefore, it will capture monoclonal anubody-dye conjugates that pass the region, showing a colored line in the control (validation) zone. The line works as a procedural control, confirming that proper sample volume was used and the reasent system worked. If insufficient sample volume is used, there may not be a control line, indicating the test is invalid.

#### Materials Provided

The AccuSign" DOA 4 test kit contains all the reagents necessary to perform the assay

- AccuSign" DOA 4 device. The test device contains a membrane coated with drug conjugates in a protein matrix and a pad containing mouse monocloral anti-THC antibody-dye conjugate, mouse monoclonal anti-opiate antibody-dye conjugate, mouse monocional anti-benzoylecgonine antibudy-dye conjugate, and polyclonal sheep anti-amphetamine antibody-dve conjugate in a protein matrix.
  - Disposable sample dispenser.
  - Instructions for use.

#### Precautions

- For in vitro diagnostic use only.
- Avoid cross contamination of urine samples by using a new unne specimen container and dropper for each unne sample.
- This test kir does not comain any HIV or hepatitis infective components. However, unne specimens are potentially intectious. Proper handling and disposal methods should be rollowed.
- according to good laboratory practices. The AccuSign" device should remain in its original scaled pouch until ready for use
- Do not use the test kit after the expiration date.

Storage and Stability The AccuSign" DOA 4 test kit should be stored at 2-30°C (35-86°F)

#### in the original scaled pouch. The expiration dating was established under these storage conditions. Specimen Collection and Preparation

Approximately 150 µL of uring sample is required for each test. Fresh unne specimens do not require any special handling or pretreatment. Specimens should be collected in a clean glass or plastic container. If

- The Control/Validation line indicates: If the proper amount of sample was used;
  - If the sample wicked:
  - If the procedure was followed properly If no control line appears, the test is NOT VALID. Repeat the test using a new device, and follow the procedure carefully.
- OR THC (-) THC (+) THC (-) INVALID OPI (-) OPI (-) OPI (+)

COC (-)

AMP (-1

COC (+) AMP (-) . . . etc. Negative (-) = Control line and Specific Drug line

testing will not be performed immediately, specimens should be refrigerated (2-8°C) or frozen. Specimens should be brought to room temperature before testing

Specimens containing a large amount of particulate matter may give inconsistent test results. These specimens should be clarified by centrifuging or allowing to settle before testing. Test Procedure

#### The test procedure consists of adding the urine sample to the Sample

well of the device and watching for the appearance of colored lines in the result window Test Protocol

- 1. For each test, open one AccuSign" DOA 4 pouch and label the AccuSign device with the patient ID.
- 2. Holding the dropper vertically, dispense 3 full drops (150 µL) of the urine sample into the Sample well
- 3. Read the result after 5-10 minutes.

### Interpretation of Results

Negative: The appearance of a readish-purple Control line (C) and a line for a specific drug indicates a negative test result; i.e., no drug above the cutoff level has been detected. The color intensities of the Control line and specific drug line may not be equal. A negative test result does not indicate the absence of drug in the sample, it indicates only that the sample does not contoin drug above the cutoff level in qualitative terms

Positive: The appearance of only a reddish-purple Control line and no distinct line next to a specific drug name indicates the test result is positive for that arug (i.e., the specimen contains the drug at a concentration above the cutoff level). A positive test result does not provide any indication of the level of intoxication or urinary concentration of the drug in the sample; it indicates only that the sample contains drug above the cutoff level in qualitative terms.

Invalid: A distinct Control line (C) should always appear. The test is invalid if no Contro. line forms at the C position. Such tests should be repeated with a new AccuSign" DOA I test device.

Examples of possible results are shown in the diagram above.

PAGE 12/33 \* REVD AT 5/26/2604 2:45:43 PM (Eastern DaySight Time) \* SVR.UBPTO-EFXRF-3/26 \* DNE;2731254 \* CBID.Dan SUBVan Jr. \* DURATION (mm-44):22-32

- THC (-), Opiates (-), Cocaine (-), Amphetamines (-): Five residish purple lines-one Control line at the C position and one each as the THC, OPL COC, and AMP notitions
  - THC (-), Opiates (-), Cocaine (-), Amphetamines (+): Four reddish-purple lines-one Control line at the C position and one
- line each at the THC. OPI, and COC positions; no line at the AMP position. THC (+), Opiates (-), Cocaine (+), Amphetamines (-). Three
- reddish-purple lines one Control line at the C position, one line each at the OPI and AMP positions; no lines at the THC and COC positions THC (-), Opiates (+), Cocaine (-), Amphetamines (-): Four
- reddish-purple lines-one Control line at the C position and one line each at the THC. COC and AMP positions: no line at the OPI position
- There are other possible results, depending on the combinations of drugs present in the urine sample.

Note: A very fami line for a specific drug in the result window, visible in 10 minutes, indicates that the amount of drug in the sample is near or below the cutoff level of the test. These urine specimens must be retested, or confirmed with a more specific alternative method such as gas chromatography/mass spectrometrs, before positive determinanone are made

#### Limitations

- The test is designed for use with unadulterated urine only.
- There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine sample than those listed in Table 4 below, may interfere with the test and cause
- erroneous results Adulterants, such as bleach and/or alum, in urine specimens ma produce erroneous results regardless of the method of analysis If adulteration is suspected, the test should be repeated with a new
  - This test detects only the presence of THC metabolites, optates, cocaine metabolite, amphetamines, and/or their metabolites in urine. A positive test result does not provide any inditation of the
- level of intoxication or urinary concentration. The test result read after 10 minutes may not be consistent with the original reading obtained within the 10 minute reading period. The test result must be read within 10 minutes of sample applica-
  - Certain medications containing opiates or opiate derivatives. amphetamines, or methamphetamines may produce a positive result in any chemical or immunological assay. Additionally, foods and tea containing poppy products and/or cora leaves may produce a positive result. Prolonged passive smoking of THC may also produce a positive result.

#### **User Quality Control**

Quality Control: Control standards are not supplied with this kit: however, it is recommended that a control be tested as good laboratory testing practice. NIDA recommends that positive quality control specimens be at or near the outoff concentration. For information on how to obtain controls, contact PBM's Technical Services. Before using a new kit with patient specimens, positive and negative corrects should be tested to confirm the test procedure, and to verify the tests produce the expected Q.C. results. Q.C. specimens should also be run anytime there is any question concerning the validity of results obtained.

Process Control. The Control line can be considered an internal process control. A distinct reddish-purple Control late should always appear if the test procedure is performed properly, an adequate sample volume is used, the sample and reagent are wicking on the membrane. and the test reagents are working. If the Control line does not appear in the control or validation line area, the test is invalid and a new test should be performed. If the problem persists, contact PBM for technical assistance

#### **Expected Values**

AccuSign" DOA 4 is a qualitative assay. The amount of drugs and metabolites present in urine cannot be estimated by the assay. The assay results distinguish positive from negative samples. Positive results indicate the samples contain the specific drug above the cutoff concentration.

#### Performance Characteristics

The AceuSign\* DOA J Panel Assay detects THC, opintes, cocuine. amphetamines, and their metabolites at cutoff levels based on the recommendations of the National Institute on Drug Abuse (NIDA) for screening of these drugs in urine.144

THC	11-nor-Δ*-THC-9-carboxylic acid	50 mg/mL
OPI	Morphine	300 ng/ml.
COC	Benzoylecgonine	300 ng/mL
AMP	D-Amphetamine	1000 ng/mL
The accuracy commerciall	of AccuSign" DOA 4 was evaluated y available immunoassay (Syva* EM.	in comparison to a

these four drugs. About 1000 random clinical samples for each drug, including at least 250 positive samples above the cutoff level for each of the four drugs, was tested by both procedures, using the cutoff values listed. Complete agreement was observed in > 99% of the sumples as shown below (Table 1.)

Table 1. Accuracy: Comparison of AccuSign" DOA 4 with Syva\* EMIT\* II Assay C. ACMUTE II OTHER

	Syva-Emil-II (IHC)			
		Positive	Negative	TOTAL
AccuSign"	Posiuve	305	5	310
DOA 4 (THC)	Negative	11	680	691
TOTAL		316	685	1001
	Sy	va*EMIT* I	I (OPI)	
		Positive	Negative	70741

AccuSion" Positive 2.10 749 DOA 4 (OPI) Negative 716 TOTAL. 250 716 966 Syva\*EMIT\* II (COC) Positive Negative AccuSign" Positive 362 363 DOA 4 (COC) Negative 13 644 658 376 645 1021

Syva\*EMIT\* II (AMP/MET) Positive Negative TOTAL AccuSign" Positive 185 n 185 DOA 4 (AMP) Negative 291 295 TOTAL 189 291 480 Relative Sensitivity Relative Specificity THC 96 5% (305/316) 99.2% (680/685) Opinies

In a separate study mens confirmed as	AccuSign" DOA 4 was	evaluated against speci-
Amphetamine	97.8% (185/189)	> 99% (291/291)
Cocaine	96.3% (362/376)	99.8% (644/645)
Opiates	99.6% (249/250)	> 99% (716/716)

results below demonstrate the excellent correlation of AccuSign DOA 4 with GC/MS (99% agreement). (Table 2.)

Accuracy: Comparison of AccuSign™ DOA 4 with

	GCIMS ASSAY		
		AccuSign~	GC/MS
THC	Positive	87	88
	Negative	1	0
OPI	Positive	73	74
	Negative		0
COC	Positive	77	78
	Negative	1	ő
AMP	Poritivo		

#### Precision and Accuracy

The precision of the AceuSign " DOA J Panel Assay was determined by carrying out the test with senally diluted standard drug solutions. About 98% of the samples containing cocaine, opinies, or amphetamine and about 90% of the samples containing THC concentrations 25% over the cutoff level consistently showed positive results.

The study also included over 40 samples ± 25% cutoff level as a challenge of cutoff precision. These results were found to be consistently in agreement with expected test results.

#### Distribution of Random Error:

Negative

Twenty (20) blind samples prepared by spiking various concentrations of cocaine, THC, morphine, or amphetamine were separately tested by two operators. The test results from the two operators showed complete agreement

## Reproducibility

The reproducibility of the test results of the AccuSign\* DOA 4 Panel Assay was examined at three different sites using a total of 15 blind controls, consisting of 5 negative samples, 5 moderately positive samples, and 5 strongly positive samples (i.e., a concentration 3 times the cutoff level). The results obtained at these three sites with these controls demonstrated 100% agreement with each other.

#### Specificity

The following tante lists compounds that are unrected by the Accubign DOA 4 test. The specificity of the Accusign DOA 4 test was determined by adding various drugs and drug metabolites to drugnegative urme specimens and testing with the AccuSign" DOA I test kit. The results are expressed in terms of the concentration required to produce a positive result. (Table 3.)

#### Table 3. Specificate

Parent Pending

	(ng/mL)	% Cross- reactivity	
THC			
Canashinol 11-nor-4'-THC-9-COOH 11-nor-4'-THC-9-COOH 3'-THC 4'-THC OPI	15,000 30 50 25,000 10,000	0.3 160 100 0.2 0.5	
Codeine Glucuronide	300 300	100	

AccuSign" is a Trademark of Princeton BioMediach Corporation

Hydrocodone 60 Hydromorphone 600 90 Leventaged 5000 6 Mependine Morphine 300 100 Morphine-3-6-D-glucuromide 500 60 Nalorphine 1.000 30 Nalovano 100,000 0.3 Norcodeine Oxycodone 0.1 20,000 Oxymorphone 60,000 Procume HC1 100 000 Thebaine 5,000 COC Benzoyleogonine 100 Cocame HCI 500 Ecgonine HC? 1.000 AMP D-Amphetamine Loog L-Amphetamine 7,000 D.L. Amphetamine solfute 1,000 100 p-OH-Methampheramine 10,000 Methylenedioxyamphetamine 200 Methylenedioxymethamphetanine 10,000 8-Phoneshylamone 20,000 Phentermine 5,000 20 Trypiamine 100,000 3-OH-Tyramine do ivo

The following compounds show no cross-reactivity when tested with AccuSign" DOA data concentra

Table 4. Non C	oss-Reacting Compour	nds
Acetamophen Acetylsalicylate Amunopyme Amitriptyline Amoxapine Ampacillia Amoxapine Appomorphine Ascorbic scied Atropine Bentocame Bentocame Bentocame	Dextropropolyphene Diszepum Diphenythydantoin Epinephine Erythrostycan Estnol Centisse actu Glutethimide Gustacol glycorol ether Hotrocaturousazate Imagramene Lidocume	Naproxen Novethendrone Penticillin Pentobarbital Phenobarbital Phenobarbital Phenobarbital Phenobarbital Phenobarbital Phenobarbital Terracycline Tearlaydrozoline Tearlaydrozoline Tearlaydrozoline Tearlaydrozoline
hlorpheniramine	Methadone	Tryptamine

### Methyprylon

References Hawks RL, Chan JCN, ods U. me Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73; 1986.

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- Tiesz, Norbert W. Teuthook of Chinical Chemistry, W.B. Saunders Company 1986, p. 1735. 3 Stewart DJ, Inobe ! Duranion M. and Kalow W. Clin. Phormacol.
- Ther. 1979.25; 2: 4-6. Ambre II. 4nal. Toxicol. 1983:9 241-5.
  - Baselt RC, Disposition of Taxi. Drugs and Chemicals in Man. 2nd Ed. Davis, CA: Biomedical Publ., 1982 p.488.
    - Blum K. Handbook of Abasable Drugs 1st ed. New York, Gardner Press, Inc., 1984

Chloroquine

Princeton BioMeditech Corporation P.O. Box 7139, Princeton, New Jersey 08543-713; U.S.A. 4242 U.S. Route 1, M. mmouth Junction, New Jersey U8852 1985 U.S.A. Tel: (908) 274-1000 Fax: (908) 274-1010

10 100A DOM

P-5843-00

# Accusian BAR

New One-Step Barbiturates Test

For in York Forence Use Con-

Simple One-Step Immunoassay for the Qualitative Detection of Barbi larates in Urine

# PBM

Candry No. 7420-748 23 Fin Am Dick 200 10 10 Jun Au

Inlended Use

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Summary and Principle of Procedure liabeause are a grape of Manisch domestics to the me and Theretan is depress, the deposits decreased on and Theretan is depress, the deposits from the me and Theretan is depressed, the equity on time and the second of the second of the second of the primition of the second of the second of the primition of the second of the second of the primition of the second of the second of the primition of the second of the subjumps and many conditions and conditions and the second of second of

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# Materials Provided

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#### Precautions

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7 or is procedure remains of adding the cases sample suche 7 in its well of the device and matching for the appearance t circlared lines in the cesult window

1. For each test, open one AcouSign \* BAR pouch and label the AccuSign" device with the pa-

2. Holding the dropper vertically, dispense 3 drops (150 pt.) of the urine sample into the Sample well (S). 3. Read the recult after 3 minutes, but within 10 minutes of sample addition

Interpretation of Results Negative: Two lines The opposition of two miles. pupil inc.-out wife less wades (Translite print mile.

Council wandow (C) - real street a property and area in a country barbonemes above the cutoff level have been decented. The cube intensty of the Ten has may be wraken or unauger then the of the Control line. A negative ice would don't use never manifested convents absence of drop on the semple or only indicates the sample sharp our numbers drop, after a the coast? Arrel on questioning server Finding: On Law The apparation of only an arother-

people in a mile if a record some law (C) and an distance have as the Test wandow (T) such as take and south reper away to g. the spectrum eastern highlantage or a concentration store the current levels of passeve test reach does not permit our ordination of the lot of special and service and service and alon of the drug is the sample; it only indicates the sample constructing about the completed in qualitative terms. Invalid: A distinct colored line should always appear in the Consultrandow (C) The true a straid of no line from suite Control tredge (C) both tive though be reported with a new Acrashge" BAR icu deves

Note: A very first har on the Test worden (Ty visible in 10' omittee), that the amount of historical set the sample of his less, These same specified in the case fixed of the less, These same specimens must be reason to confirmed with a more specimens must be reason to a confirmed with a more specific electronics must be reason to the gas in demonstrating the first set in the same specific electronics must be desired.

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# RUGTEST

Presents the AccuSign DOA Series

# One-Step Orug Testum Results in Only 2-5 Minutes



- ( Easy to Read Color
- () Highly Sensitive
- ( ) Built-In Test Control
- ( No Refrigeration
- () Eliminates Timino
- () Simultaneous Testino Capability of Multi-Oruos

Tests are available in single or multiple test ganels for the following drugs: **Amphetamines** Cocaine Barbiturates Methamphetamines Benzodiazepines Morohine/Opiates

PC.P THC (Marijuana)

Watch us for More Tests & New Technologu

FRHIBIT 3

# AccuSign" DOA Series

# Test Procedure



- Using the plastic pipette, add 3 drops of urine sample to the Sample Well.
- 2. Read results in 2 to 5 minutes (within 10 minutes). 3. Interpret Test Results Window:
  - CONTROL LINE A colored line indicates
    the test is complete and the system has worked
    properly.
  - NEGATIVE A colored line for the specific drug indicates the test is negative and the drug was NOT DETECTED.
  - POSITIVE No colored line for the specific drug indicates the test is positive and the drug was DETECTED.

Tests Manufactured by Princeton BioMeditech Corporation

# Samples





THC (-) negative Opiates (-) negative Cocaine (-) negative Amphetamines (-) negative

Opiates (-) negative Cocaine (+) positive Amphetamines (-) negative

For information or to place an order call:

UNIVERSAL DRUG TESTING 476 ROUTE 51 LARGE, PA 18005

# Visualine<sup>™</sup> II

# One Step Drug Screening Test

#### AVITAR TECHNOLOGIES, INC.

produces, markets and distributes medical devices for the health care industry.

Avitar now distributes rapid Tests for Drug Abuse that are:

- accurate
- sensitive
- simple to use

The Visualine™ II tests' which have FDA approval to market are:

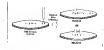
- Cocaine
  - Morobine
- · Cannabinoids (THC)
- Benzodiazeoines

The tests are composed of preformulated dry magnetic arranged on a power, emberges support in a commental cassests. To perform the tests, list adds after drops of since to the sample will be finded and with the minister. Since are then easily read in the results window as the presence or absence of a red line. A built in reference control essues that the sample has been added and that the test is desirble. The tests are based on the review lateral (in micro-putche tests are based on the review lateral in clinical trids at a major university. The Vissaline' It tests are deligned to mist MNA proposed cold freely.

<sup>1</sup> A test for Methamphetamine is available for uses that do not require FDA approval to market



Visualine"II test device and pipette.



Simple to use and simple to read

For information contact customer service at 1.800.255.0511

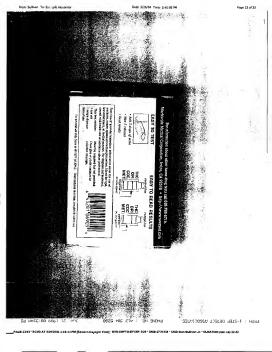
AVITAR TECHNOLOGIES, INC. 65 Dan Road, Canton, Massachusetts 02021

EXMISIT 4



EXHIBIT 5

PAGE 2253 \* RCVD AT 5/26/2004 2:45:45 PM (Eastern Daylight Time) \* SVR.USPTO-EFXRF-0/26 \* DNIS: 2751254 \* CBID:Dan Bullivan JL. \* DURATION (min-se); 22-25



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Resignation Harld Service Office, fac PO Box 8950 Van Nays, CA 91409 818/773-2040 Other City, CA 90231-3435 910/736-9505 Partito Assepteet, for PD Box 3425

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Commonly Asked Questions:

HOME DRUG TEST

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Instructions for Us



40. The least received by the same shade or intensity. The control one may look darter than a test line, or vice vesse.

Methamphetamines Morphine/Opiates, Marijuana (THC) First Check Cocaine, &

1-21Eb DELECT RESOCUELES

Sufficency: \* DURATION (mm-ssk:22-32

When the need to know is....now

Simple - one step

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The test is aexisting properly as long as a reduced line is visible in the Control window. The result is negative for manusary.

and made of the North American land and the land of th

Easy-to read

Confidential

Result in 5 minutes

190 21t : TON BROHA

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completely before use.

Store at 40-86°F (4-30°C) For external use only

FOR EDUCATIONAL USE ONLY

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First Check®

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First Check" New to be taken internally Marijuana (THC), Morphine(Opiales, Cocaine

Methamphetomines

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L'OSULTA

2. Collect terms sumple in a Instructions Open the water pour exampliation glass on a flat surface with Test card, and set the card on ratione the Frest Check

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If no line appears in the County washing appear in the Control (upper) strakes A distinct selected line should always Insolid Test drug taken (cocaine)s





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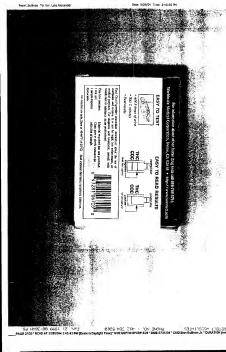
The First Check® char-Stop Home Drive Test in this manage ON BRIDGE

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Proving Up Drug Pree: A Parent's Guide to Provedien, II'S De comune of Esseabon, Mathington, D.C., MCATA Fridancies Mo rporteent of Hrs.OV and Honson Sciences, 1995 reging Wash Drug Proc. A Guide for Parents, Grandputests and Other Caregreers, Costor for Subsquare Alesse Procession, U.S.

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Services fishings, or page 4 of this passible for Suppor

Support Group I teadquarters ALACTOR Facility Group Headquarters P.O. Box 862 ACC. 000.000 Michell States Place Service Office, Inc. PO Box 9949 Van Noys, CA 91469 2187775-9989

Remitte Assessment, Inc. p.G. Bea 3475 Cuber Chy, CA 90211, 3475 S00776-9886

WORLDWIDE MEDICAL

physician to a recommended laboratory in select the same sample Save the unused portion of the urine sample. Ask you family

pamphies for Support Group intermation. Covenings and Community Services Issings, or page 4 of the Check with your physician, your phone directory also provides sources of excisional under "Alcehol and Drug Abrist" in the Group et constant and education elegations for more information urder "Alcahol and Days Abuse" in the Government and Control physician, your protest rectory also provides sources of acceptants continues to relate, seek professional help. Check with your

wide Medical Corporation of July Street

Commonly Asked Questions:

control from many back during them a legal lead, or work winds No. The loses need not be the same shade or intensity. The

A CONTRACTOR OF PERSONS negative result (3 lines, 1 line in Control window and 2 lines The lest should be read within 10 minutes for best results. Tes excess rat move disappear

palest and the second s The test is working properly as long as a othered line is woods in the Central working. The result is negative for manusars and is positive if there is no line next to a drug material the feet cottone if here are also 2 lines in the Test wirdow. The result

When the need to know is....now

& Cocaine Marijuana First Check\*

you do not record to well. If a live in the local window is not clear ing the result. However, if your lest clearly above negative (3 ties, a ties in the Control window and 2 tiess, a tie test window). Yes, set recovernment that you want the full 5 manufact before need your regular with more accounte mer 5 mandes. Most regular

Confidential Easy-to read Simple - one step

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of this particular supplies outside data on drug usage among coaine or the senousness of accessoral drug usage, prige 4 suedion the engagement of besting then or her for manyuma and Result in 5 minutes

into assert in a street the interest of marijuant and consiste. It is not for legal, time enfort control or medical purposes. For disgreets and receivent, consult with a limith care in First Check Marijagua & Cocome provides monodain abduse ofere professional.

Read the following directions completely before use

Store at 36-86°F (2-30°C) For external use only

Hims Check\* is a regularized tradecook of Northead Mexical Chapter in

FOR EDUCATIONAL USE ONLY

HOME DRUG TEST instructions for Use

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"Aprijanst meinamand 43% in junier ligh (grotia o 8) eel 28 'e e bigh sabel sustems (prodes 9-12). valued Parent' By warm hatter for Dog Ethication, for (Talbitis) they want the board survey (September 25, 1926)

Marjeres Attorpososs World Services Office PO Box 2912 Van Noya, CA 91484 (DC/766 6179

boars of exposure and remain detectable for 3-10 days tilevaled levels of urinary metabolities are found withto and the disprior is 90-120 minutes after one eightete effect of snucking manjutuse occurs in 20-30 minutes may be associated with behavioral disorders. The peak

Couring derived from the leaves of coca plant is

interpret result ways appear in the Control (upper) Invalid Test

Limitations

Lifer smooking

Instructions

Open the sealed pouch, remove the First Check\*

card, and set the card on a flat surface with Test

frank torse delirium. Long term, relatively heavy use cause transient episodes of confusion, anxiety, or even comony and exciptiona use slows learning. Also, it may cuphoric effects. Users have impairment of short term counsbinous). When ingested or smoked, it produces THE is the printery octive ingredient in multiplina

Collect to the sample in a citori plustic of guar to sample and release pressure on press bulb het ween Sel OACL Samble Watt surple depen container and Control wandows facing up bulb. Sample will fift half of dispenser take finger, insert dispenser opening in



does not provide any information about the amount to asuble. The ast intruenent must be followed precitely The First Check\* One Step Home Drug Text is use or window. If no line appears in the Control window, do not A distinct colored line should at

and cousine or their metabolites in urine. A positive iest The test detects only the presence of manjutate UFIC.

level of inflationation

Adulterants, such as bleach and/or alum, in a utine satural The test is designed for use with unadulier and urine, only oral administration and excreted in the urrac primarily

as benzoylecgonine in a short time. Benzoylecgonine Cocame is used by smoking. Intravenous, intransist or rate, dilation of the populs, fever, tremors and aweating chological effects are accompanied by increased hear and a sense of increased energy in the user, these pay local anesthetic. Cocaine induces emplicana, confidence potent central nervous system (CNS) scientists and a

First Check

issue alterediate as or expense 0.5-1.5 (purs) and car generally be detected for 30-00 allinger are a substance of a memory of participation of the series

# Before you begin

not use after the expiration date stamped on the purkage he test kill contents shown, below. Store at 36-86° F (2) founing the test. First, make sure you are familiar with C) in the scaled pouch, away from direct smlight. Do Read all the information in this pamphiet before per



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window means the sample contains Cosilise. Three horizontal lines, one lute of

the Central (upper) wandow also

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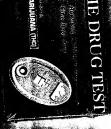
may produce an errorsous result. If adulteration is six Prolonged exposure to second and interjugate stroke into has been refrigerated, allow sample to come to rount ten-Unine cample should be at room temperature. If sumph tion. A result read after 10 number may not be accurate. The result must be read 5:10 minutes after sample applicapected, the test should be repeated with a new times stumple perative before testing

til result is read. Read the result after 5 minproduce a positive result

utes but within 10 minutes.

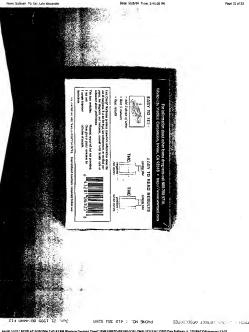
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reput; with the cheenly requisition is minute. To be super of A positive (1) has no Constal wondow and no lines in Test wendow), wind 3 minutes sub milibe more accurate after 3 minutes. Mice inspanya land

When a my child refuses to gap a crime sample? but no kingst than 40 minutes

can, your priorie directory see provides sources of accor-Pathenily gain your chiefs cooperation with the universioning that it is then well no that you are puriseding. Should your chief question the implementation of testing from or her for resultance or numby Semicos listings, or page 4 of this pemphid for Suspon usder "Alcohol and Drug Abuse" in the Consumerit and Comsraps to setuse, seek professional help. Checkwith your physipersentent without apparations, freeza, or angel. If you child to o youth and why you, as a parent, cannot lighter this presiding. Be paraphiet expotes covers cars on markusta usasy among ou the particulateds of posterional manipulate usage, page 4 of the

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pay by the death and only a little of the pay of the Stup Internation and educatorial resources for more information

Check with your physician, your phone directory data previous sources of applicance under "Accordance Using Abuse" in the Gavennment and Commonth Services licings, or leage 4 of this panghlet for Support Group Etformation

# Commonly Asked Questions:

errent Marjasson Treats

# HOME DRUGTEST Instructions for Usa

# The leading in The State Control washes Does this

to Buth lines need not be the same shade or interally

control less may look during han the not line, or not versa

How long wall the colored line commin with all

Marijuana First Check® (THC

Lamps such of my list nood, What social ide The test should be read within 10 minutes for best results. A nega-tive result (2 m/ss; 1 less in Constituent Sovi and 1 live in Test win cosperation despitation

The fect is working peoperly as long as a colonel line is wishlo in the Control window. The result is negative for margining. If Texts no line in this fast wandow

When the need to know is....now

Simple - one ster

Dolbers to wait the full Septides before reading Darkers saizza inemite ligituardos. The result is positual albert is

could be vest. If the line in the less window as end clear, you re inos, a line in both the confied and lest windows), you do not bes, we recommend that you wan the full 3 emplos before read ng the result. However, if you sest clearly stown negative?

Casy-to-read

Confidentia

Result in 3 minutes

affects the ask of morneaden. It is not a to find to First Chee C. Marijama prenices marcina. Protest \*rokssvundt treatment, currently within a health pure or selection is not enjournment, or medical property for discussive

> ages 271

Read the following directions completely before use

nump

Store at 36-86TF (2-30°C) For external use cally

But Check an what of transcended to Market Street of Congress FOR EDUCATIONAL USE ONLY

Save the unused portion of the urine sample. Ask your family physician for a recommended laboratory to reflect the same

6d HEOM:80 6661 TZ



# Marijuana (THC

suptoric effects. Users have impairment of abort term (cannabinoids). When ingested or smoked, it produces THC is the primary active ingredient in marriants Collect unice sample in a clean plastic or glass confainer and Control windows facing up. and, and set the card on a flat surface with les-



no fine in the first wandow means the One line in the Control window and







Before you begin

enthalite test kill conferns shown, below. Stofe 31 30-50 it per-forming the test. First, make sure you are familia

Read all the information in this pumphlet before First Clack

hours of exposure and remain detectable for 3-10 days Hievated levels of urisary metabolites are found within and the diamtion is 90-120 minutes after one eigarette effect of smoking mustjuana occurs in 20-30 minutes may be associated with behavioral disorders. The peut frank toxic delirium. Long tents, relatively beavy use cause transient episodes of confusion, anxiety, or ever memory and marijuses we slows learning. Also, it may

PLACE SIEGNATURE

Allow the test card to remain undisturbed untiresult is read. Read the result after 3 minutes but within 10 minutes

to not use after the expiration duke stamped on the pack 2. O C) til the scaled poich, flerty from offert stillight

Instructions

Open the realed peach, remove the Pirst Check

Kesulis

Wat at least 3 minutes but a . . . we then 16 simules

before reading result

2 lines - negative

sampHc. of the Control (upper) window and Two horizontal lines, one in each

the line in the Cantrol window don may be lighter or darker than is no menjuana present in the unine Test (lower) window, means there no drug taken The time in the Test was

l line - positive

sample contains manys as drug taken

interpret result window. If no line appears in the Countril wandow, do no ways appear in the Control (apper) A distinct colored line should at Invalld Test

Unite sample should be at room temperature. If setup son. A result read offer 10 measles may not be accurate. The result must be read >-10 minutes after sample applic pocted, the test should be repeated with a new tarine sample may produce an erroreous result. If adulteration is sue The test is designed for use with unadulectated unite, only window) does not provide any information about the as metabolites in unite. A positive test (no line in Test The test detects only the presence of marijuana (THC) or usable. The test instructions unsit be followed precises The First Check" Cite-Step Home First test is not to Limitations Adulterants, such as bleuch and/or alum, at a trine sample arrant or level of infloantation

between period period tias open reiniginated, allow simple to come to rocks to the renduce a positive result Prolonged exposure to secondrand marijuana smoke way